

REMARKS

Claims 21-63 are currently pending.

Rejection Under 35 U.S.C. § 112

The Examiner rejected claims 21-63 under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner, in rejecting the Applicant's previously filed arguments of November 28, 2003, restated his July 29, 2003 rejections and adds:

[W]herein Applicant's arguments assert that the core-committee is to perform all of the above functions. However, absent from the specification are guidelines/decisions by which the core-committee is to perform the above functions. For instance, by what manner/procedures (i.e. the steps of analysis/assessment/evaluation) does the core-committee review publications? What parameters define the decision process so that adjustments can be made to the rules? One of skill in the art would be unable to assess the scientific literature without a set of guidelines by which to follow. The derivation of said "rules" is considered undue because it is unclear what the core-committee is performing procedurally with respect to the scientific literature and assessment of values. The derivation of said "rules" is not considered routine in the art and would require further inventive skill to develop said "rules". Thus, the original disclosure fails to provide one of skill in the art proper guidelines to make or use the claimed method, computer program device and computer program carrier.

See page 4, lines 3-14 of the Final Office Action dated February 24, 2004.

The Examiner raises several objections, all of which relate to the fact that the present specification does not give a detailed description of exactly how to derive each rule in the rules database. However, the applicant submits that it is not necessary for the specification to provide this level of detail because a person of ordinary skill in the art is already capable of deriving the rules to be used for the rules database and thus does not need to be taught how to do this by the present specification. See e.g. MPEP Section 2164.05(b).

In this regard, the Examiner's attention is directed to the attached Declarations of Charles Boucher, PhD and Andrea de Lucia, M.D., which address this subject.

These declarations first point out that the level of skill in the art is high. Specifically, The state of the prior art is evidenced by, for example, two of the documents of record in the present application, namely, "CTSHIV: A Knowledge-Based System for the Management of HIV-infected

Patients,” Pazzani et al., *Proceedings: Intelligent Information Systems, IIS’ 97* (CAT. No. 97TB100201), 1997, pages 7-13 (hereinafter “Pazzani et al.”); and “Knowledge-Based Avoidance of Drug-Resistant HIV Mutants,” Lathrop et al., *American Association of Artificial Intelligence*, 1998, pages 1071-1078 (hereinafter “Lathrop ’98”). Lathrop ’98 describes the CTSHIV system
5 that is employed in the method of Pazzani et al.

According to the declarations, Lathrop ’98 and Pazzani et al. demonstrate that a skilled person already knows how to implement a rules database wherein a suitability indication is based on a value indicating resistance level of the genotype for that drug, i.e. element (a) of claim 1 of the present application. See paragraphs 7-10 of the declarations.

10 In addition, the declarants are of the opinion that Lathrop ’98 demonstrates that, as of 1998, a skilled person was capable of implementing element (b) of claim 1 of the present application, namely, basing a suitability indication on a value indicating the confidence in the value indicating a resistance level of the genotype for that drug. See paragraph 11 of the declarations.

The declarations also address of the other factors which must be considered in an
15 enablement rejection according to *In re Wands*, 858 F.2d 731,737,8 USPQ2d 1400, 1404 (Fed.Cir.1988) and MPEP §2164.01(a). In each case, the factual circumstances of the present case favor a holding of enablement. For example, the level of predictability in the art is high (Declarations, paragraph 12), the specification provides detailed direction as to how to carry out the invention (Declarations paragraphs 13-16), and the specification contains an extensive working
20 example at pages 7-12 (Declarations paragraph 17).

Finally, in the opinion of both the clinical microbiologist with a doctorate in medicine, Charles Boucher, and the medical doctor, Andrea de Lucia, the skilled person is capable of implementing the present invention with essentially no experimentation whatsoever. See e.g. paragraphs 18, 20, 22, and 24-26 of the declarations.

25 According to MPEP 2164.04, the initial burden is on the Examiner to demonstrate lack of enablement. In the present case, the Examiner has only given reasons in support of the position of lack of enablement, but has presented no evidence in support of this position. The applicant has now presented the following evidence in support of the position that the specification is enabling:

- (1) Pazzani et al.,
- (2) Lathrop '98,
- (3) The Declaration of Charles Boucher, and
- (4) The Declaration of Andrea de Lucia.

5 In view of the foregoing, the balance of the evidence weighs heavily in favor of a holding of enablement and thus the rejection under 35 U.S.C. §112 should be withdrawn.

With regard to the Examiner's specific objection that the specification does not teach how the conferred resistance by substitution is derived and a value is assigned indicative of resistance level, persons of ordinary skill in the art already know how to create such a rules database using
10 their common general knowledge. See e.g. Declarations paragraphs 7-10, Pazzani et al. and Lathrop '98.

As to the objection of the Examiner on how the evidence in the scientific literature is assigned to indicate confidence levels, the specification, page 5, line 35 up to page 6, line 6 clearly states the confidence levels. The scientific articles upon which the levels will be based will
15 describe whether the drug result is based on suggestive evidence, is proven *in vitro*, or is proven *in vivo*. The core-committee will finally assign the confidence level by reading the scientific articles and objectively determining which of the confidence levels applies. The end user is easily capable of making these assessments. See Declarations paragraphs 14-15. Moreover, Lathrop '98 makes it clear that many expert systems already existed in 1998 which applied weighting based on
20 confidence levels, further demonstrating that a skilled person is capable of carrying out this step of the claimed invention. See Declarations, paragraph 11.

As to objection of the Examiner on how to combine and weigh resistance level, drug level, confidence level, and clinical experience to assign a value indicative of suitability, the enclosed Declarations explain that the skilled person, as of the filing date of the present application, was
25 capable of doing this. See e.g. Declarations, paragraphs 7-10, and 14-26.

Finally, the Examiner objects to the present claims on the basis that no specific algorithm/steps/procedures are given for derivation of the first, second and third values referred to in the claims. The reason for this is that no specific algorithm/steps/procedures are required for derivation of the first, second and third values, other than that the skilled person take into
30 consideration certain information in deriving those values. Since the skilled person already does this every day in their current practice (See Declarations paragraph 8), and expert systems already existed at the time the present application was filed that employed suitability levels and used

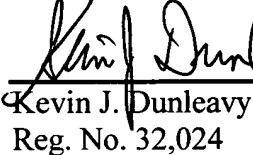
weighting based on confidence values (See Declarations paragraphs 9-11), there is no need for the present specification to explain, in precise detail, how to go about doing this.

Applicant respectfully submits that all the claims are in condition for allowance and requests that the §112, first paragraph rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, and the submission of the enclosed declarations of Charles Boucher and Andrea de Lucia, it is believed that this application is in condition for allowance.

Respectfully Submitted,
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